Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 021217
Company: SPECGX LLC

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021217s023s024lbl.pdf#page=30)
- REMS (http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021217s000SumR.pdf)

Products on NDA 021217

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	R
EXALGO	HYDROMORPHONE HYDROCHLORIDE	8MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	R
EXALGO	HYDROMORPHONE HYDROCHLORIDE	12MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes
EXALGO	HYDROMORPHONE HYDROCHLORIDE	16MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes
EXALGO	HYDROMORPHONE HYDROCHLORIDE	32MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021217

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
03/01/2010	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD	Label (PDF) (https Letter (PDF) (https Review (https://wv Summary Review

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
09/18/2018	SUPPL-24	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
09/18/2018	SUPPL-23	REMS - MODIFIED - D-N-A	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
05/26/2017	SUPPL-21	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
12/16/2016	SUPPL-19	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
09/30/2016	SUPPL-20	REMS - MODIFIED - D-N-A	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
04/20/2016	SUPPL-17	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
06/26/2015	SUPPL-15	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
06/02/2015	SUPPL-9	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
08/19/2014	SUPPL-14	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
06/17/2014	SUPPL-12	Labeling-Medication Guide, REMS-Proposal, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
04/16/2014	SUPPL-13	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
04/15/2013	SUPPL-6	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
03/18/2013	SUPPL-5	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
08/24/2012	SUPPL-4	Labeling-Package Insert, REMS-Modified	**Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
07/09/2012	SUPPL-2	Labeling, REMS-Modified	**Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
03/24/2010	SUPPL-1	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**

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Labels for NDA 021217